EXHIBIT E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	: :	**CIVIL ACTION NO. 2:12-md-02327** **MDL No. 2327**
This Document Applies To All Actions	: :	Judge Joseph R. Goodwin

ETHICON INC.'S SECOND SUPPLEMENTAL RESPONSE TO PLAINTIFFS' FIRST SET OF INTERROGATORIES

Defendant Ethicon, Inc. ("Ethicon") submits the following second supplemental objections and responses to Plaintiffs' First Set of Interrogatories.

OBJECTION TO PLAINTIFFS' DEFINITION

1. Plaintiffs define "Pelvic Mesh Products" to include Prolene mesh and Prolene Soft Mesh. Ethicon objects to each and every interrogatory related to Prolene mesh, Prolene Soft Mesh, and any other hernia mesh. Ethicon objects to the production of any documents or information related to Prolene mesh, Prolene Soft Mesh, and any other hernia mesh other than as set out in the following: non-privileged, responsive documents from the following centrally-stored files: Regulatory, Design History File, Trial Master Files, Quality Systems (including Complaints, Complaint Reviews, Product Quality Investigations, Corrective Action Preventative Actions, and field actions), to the extent they exist. Ethicon objects to the production of documents related to UltraPro Mesh other than certain non-privileged, responsive documents from the Trial Master Files, CAPA Reports, Non-Conformance Reports and complaint files from CHATS, as well as certain design history files and preclinical studies. Ethicon objects to the production of any other documents and information related to hernia mesh products. As these products are indicated for a hernia repair application, and given that they may potentially have been used in a gynecological application in only a handful of cases in this litigation, the burden

on Ethicon to respond to interrogatories related to these products unreasonably exceeds the possibility that any significant information relevant to these matters will be obtained. Ethicon further objects to Plaintiffs' definitions to the extent that Plaintiffs list the TVT-Catheter Guide and TVT-Introducer as "Pelvic Mesh" or "Pelvic Mesh Products." However, based on the meet and confers between Plaintiffs and Ethicon, Ethicon invites Plaintiffs to narrow the scope of their requests concerning these hernia mesh application products.

INTERROGATORIES

INTERROGATORY 1:

If at any time you applied for, supplemented, or otherwise filed or responded to any Pelvic Mesh Product 510(k), add-to-file, 522 order, or any other regulatory submission, was there any information that was required by any regulation, law or rule to be provided to the FDA or any Foreign Agency that You did not provide, for that piece of information, please specifically set forth the following:

(a) The specific type of information not provided;

(b) The date the information should have been provided;

(c) The date the information was first reported to You;

(d) How You became aware of such information. (i.e., clinical trial, animal study, literature search, add-to file, etc.);

(e) The name of anyone employed by You to whom the information was first reported;

(f) Attach any and all documents relating to any of Your responses to this interrogatory.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 1:

Ethicon objects to Interrogatory No. 1 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence

admissible at trial. Ethicon objects on the grounds that this interrogatory is not limited to any relevant time period, and seeks information that is irrelevant. Ethicon objects to this interrogatory on the grounds that it is overly broad, unduly burdensome and oppressive insofar as it seeks information relating to foreign regulatory submissions, although Ethicon is currently working with Plaintiffs to narrow and prioritize the scope of foreign regulatory production. Such information is neither relevant to the claims and defenses in this action nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing Objections, Ethicon states that it has complied with the relevant United States regulations with respect to its regulatory submissions to FDA concerning its pelvic mesh products. Ethicon is continuing to meet and confer with plaintiffs concerning information related to foreign regulatory submissions and information related to hernia mesh devices.

INTERROGATORY 2:

What warnings, information or notifications, if any, did you provide to health care providers and patients concerning the use and Complications of Pelvic Mesh Products.

Produce copies of any and all such warnings, information and notifications that relate to any of your responses.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 2:

Ethicon objects to Interrogatory No. 2 because, as worded, it is ambiguous, overly broad and unduly burdensome. Ethicon objects on the grounds that this interrogatory is not limited to any relevant time period, and seeks information that is irrelevant.

Consistent with Federal Rule of Civil Procedure 33(d), and the Protective Order entered by the Court, documents responsive to this interrogatory have been produced to Plaintiffs in the

manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. Notwithstanding, set forth are some examples of documents, though not all of the documents, which have been produced to Plaintiffs that may be responsive to this interrogatory: *See, e.g.*, Copy Review Materials, ETH.MESH.00142081-00149087 (Prod. 3); ETH.MESH.00154266 to 00170122 (Prod. 4); ETH.MESH.00311528 to 00311554 (Prod. 7); information regarding IFU documents, ETH.MESH.00521869-ETH.MESH.00523158 (Prod. 13), ETH.MESH.02340250-ETH.MESH.02342290 (Prod. 27); documents regarding copy review dates for sales, marketing and professional education materials, ETH.MESH.02330766-ETH.MESH.02330777 and ETH.MESH.PM.000065-ETH.MESH.PM.000067 (Prod. 25); Agile Labeling production, ETH.MESH.02340250-ETH.MESH.02342290 (Prod. 27); ETH.MESH.02342291-ETH.MESH.02345802 (Prod. 28); ETH.MESH.02346965-ETH.MESH.02347254 (Prod. 30); ETH.MESH.03456774 - ETH.MESH.03461142 (Prod. 34); Prolift Surgical Technique Guide (Plaintiffs' Exhibit 126, New Jersey coordinated proceeding); and website information, pelvichealthsolutions.com at ETH.MESH.PM000131 – ETH.MESH.PM.000131 (Prod. 69).

For information contained within the Instructions for Use, Ethicon states as follows:

Product	**Description**	**Dates of Use**
Gynemesh PS	Gynemesh PS IFU. ETH.MESH.02342218-49	12/4/2008 to 2012
Gynemesh PS	Gynemesh PS IFU. ETH.MESH.02342250-77	12/12/2008 to 2012
Gynemesh PS	Gynemesh PS IFU. ETH.MESH.02342278-90	6/8/2005 to 12/11/2008
Gynemesh PS	Gynemesh PS IFU. ETH.MESH.02342194-217	3/20/2003 to 3/30/2006
Prolene Mesh	Prolene Mesh IFU. ETH.MESH.02342152-54	6/18/2010 to present day
Prolene Mesh	Prolene Mesh IFU. ETH.MESH.02342102	5/29/1999 to 7/3/2011
Prolene Soft	Prolene Soft IFU. ETH.MESH.02342101	12/5/2000 to present day
Prolene Soft	Prolene Soft IFU. ETH.MESH.02342094-96	8/23/2010 to present day
Prolene Soft	Prolene Soft IFU. ETH.MESH.02342097	4/13/2009 to 8/22/2010
Prolift	Prolift IFU. ETH.MESH.02341658-1733	5/11/2010 to 9/7/2012
Prolift	Prolift IFU. ETH.MESH.02341734-1809	10/1/2009 to 5/7/2010
Prolift	Prolift IFU. ETH.MESH.02341454-1521	12/17/2007 to 9/24/2009

Product	Description	Dates of Use
Prolift	Prolift IFU. ETH.MESH.02341522-89	1/11/2005 to 12/13/2007
Prolift +M	Prolift + M IFU. ETH.MESH.02341954-2093	5/11/2010 to 9/7/2012
Prosima	Prosima IFU. ETH.MESH.02341398-1453	6/18/2010 to 9/6/2012
TVT	TVT IFU. ETH.MESH.02340402-70	11/29/2010 to present day
TVT	TVT IFU. ETH.MESH.02340504-67	10/13/2008 to 11/22/2010
TVT	TVT IFU. ETH.MESH.02340250-305	4/7/2006 to 10/7/2008
TVT	TVT IFU. ETH.MESH.02340471-503	2/11/2005 to 4/7/2006
TVT	TVT IFU. ETH.MESH.02340306-69	12/22/2003 to 2/21/2005
TVT	TVT IFU. ETH.MESH.02340370-401	1/16/2001 to (unavailable)
TVT Abbrevo	TVT-Abbrevo. ETH.MESH.02341203-67	9/10/2010 to present day
TVT Exact	TVT-Exact. ETH.MESH.02341119-202	5/4/2010 to present day
TVT Obturator	TVT-O IFU. ETH.MESH.02340902-73	5/12/2010 to present day
TVT Obturator	TVT-O IFU. ETH.MESH.02341047-1118	4/23/2008 to 5/7/2010
TVT Obturator	TVT-O IFU. ETH.MESH.02340974-1046	5/25/2005 to 4/29/2008
TVT Obturator	TVT-O IFU. ETH.MESH.02340756-828	3/7/2005 to 5/19/2005
TVT Obturator	TVT-O IFU. ETH.MESH.02340829-901	1/7/2004 to 3/4/2005
TVT Secur	TVT-S IFU. ETH.MESH.02340568-755	12/16/2005 to 9/1/2012

For TVT IFUs in use prior to 1/16/2001, Ethicon states that a third party, Medscand Medical AB, not Ethicon, manufactured the device prior to that date and thus Ethicon did not generate the IFUs during that time period. Ethicon will update this response if a copy of the applicable IFU(s) is obtained..

Regarding patient brochures for Prolift, Ethicon notes that despite diligent efforts, it has not always been able to determine the precise "in-use" dates for all materials. However, Ethicon has provided such information to the extent it is available, and will continue to do so as its investigation to identify and locate this information on a document-by-document basis continues. The earliest possible "first-use" date for any given copy review item would be the copy approval date: The latest possible "last use" date for any given copy review item would be the expiration date, subject to renewal. Ethicon has produced the protocols regarding expiry dates, which are generally linked to document types, for periods relevant to the litigation.

Regarding patient brochures for Prolift, Ethicon provides as follows:

PATIENT BROCHURES

Product	Title	Date
Prolift	"Get the Facts, Be Informed" brochure copyrighted 2005. ETH.MESH.03905968-ETH.MESH.03905975	11/09/2005
Prolift	"Get the Facts, Be Informed" brochure copyrighted 2006. ETH.MESH.03905976-ETH.MESH.03905991	11/15/2006
Prolift	"What's Happening Down There" brochure copyrighted 2007. ETH.MESH.03905992-ETH.MESH.03906000	02/07/2007
Prolift	"Stop Coping, Start Living" brochure copyrighted 2008. ETH.MESH.03906037-ETH.MESH.03906052	10/22/2008
Prolift	"Stop Coping, Start Living" brochure copyrighted 2009. ETH.MESH.03906001-ETH.MESH.03906020	11/09/2009

Color copies of these patient brochures were provided in Production 44. Additionally, copies of responsive patient brochures for pelvic mesh products have been produced in the Copy Review productions. *See also* Ethicon's Responses to Requests for Production Nos. 4, 15, 28, 29, 47, 50-52, 61, 66, 78, 81 – 86, and 99. Ethicon is also providing Plaintiffs with additional information related to the TVT family of products.

INTERROGATORY 3:

If during or after the time you marketed, sold, distributed, or produced Pelvic Mesh Products, You were aware of any complications or adverse events for which You did not provide warnings, information or notifications to health care providers, consumers, or any governmental agencies, please identify:

(a) The complications or adverse events;

(b) If the complication or adverse event was attributed to the Pelvic Mesh Product, the surgeon, both, or some other conclusion.

(c) When the complication or adverse event was first reported to You;

(d) How You became aware of complication, (ie clinical trial, study, literature search, etc.)

(e) The name of anyone employed by You to whom it was first reported, and the name of the Person who reported it to You;

(f) The identity of those individual(s) who made the decision whether or not to inform Health Care Providers, consumers, or governmental agencies of these complications or adverse events.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 3:

Ethicon objects to Interrogatory No. 3 because, as worded, it is ambiguous, overly broad and unduly burdensome. Ethicon objects on the grounds that this interrogatory is not limited to any relevant time period, and seeks information that is irrelevant.

Subject to and without waiving the foregoing Objections, Ethicon states it has complied with the relevant United States regulations regarding the reporting of adverse events and that it has complied with the relevant U.S. regulations concerning providing adequate and accurate warnings and information to health care providers, consumers, and governmental agencies. Consistent with the Federal Rules, and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. Pursuant to Fed. R. Civ. P. 33(d), the electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. Notwithstanding, set forth are some examples of documents, though not all of the documents, which have been produced to Plaintiffs that may fall within this interrogatory. *See, e.g.,* documents referenced in Ethicon's Response to Interrogatory 2; Ethicon's Response to Plaintiffs' Requests for Production of Documents Nos. 28, 35.

Further, information responsive to this interrogatory may also be found in the custodial productions from and deposition transcripts of the witnesses deposed in the New Jersey coordinated proceeding, including but not limited to the following persons: Dr. Piet Hinoul, Dr. David Robinson, Dr. Aaron Kirkemo, Dr. Martin Weisberg, Dr. Charlotte Owens, Dr. Jessica Shen, Dr. Judi Gauld, Catherine Beath, Bryan Lisa, Jennifer Paine, Sean O'Bryan, Dan Lamont,

Dr. Meng Chen, and Mark Yale. Ethicon is continuing to meet and confer with plaintiffs concerning information related to foreign regulatory submissions and information related to hernia mesh devices.

INTERROGATORY 4:

If You have received any Communications (other than lawsuits filed in any jurisdiction or attorney claim letters) concerning the safety or complications from the use of Pelvic Mesh Products please identify:

(a) the individual(s) and/or company(ies) or institution(s) who communicated with you, and if not in a written or reproductive format, describe the nature of such communication in detail.

(b) Produce any communications responsive to this interrogatory.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 4:

Ethicon objects to Interrogatory No. 4 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Ethicon objects on the grounds that this interrogatory is not limited to any relevant time period, and seeks information that is irrelevant.

Subject to and without waiving the foregoing Objections, and consistent with the Federal Rules, and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. This includes the adverse event database for all relevant worldwide adverse events that The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. Notwithstanding, set forth are some examples of documents, though not all of the documents, which have been produced to Plaintiffs that may fall within this interrogatory. *See supra* Responses to Interrogatories 2 and 3; *see also* Custodial

Productions and deposition testimony of Paul Parisi, Vincenza Zaddem, Jonathan Meek, Scott Jones; *see also* Prods. 61 and 64. Ethicon continues to meet and confer with plaintiffs concerning information related to foreign regulatory submissions and information related to hernia mesh devices.

INTERROGATORY 5:

Please identify by name and date the Persons who authored and/or received any correspondence (other than lawsuits filed in any jurisdiction or attorney claim letters) concerning whether the Pelvic Mesh Products' Instructions for Use, (IFU's) patient brochures, or related information should be modified about the complications, risks and benefits, or indications concerning the Pelvic Mesh Products. Please produce copies of any communications responsive to this interrogatory.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 5:

Ethicon objects to Interrogatory No. 5 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Ethicon objects to the extent Plaintiffs do not define "related information." Ethicon further objects to this Interrogatory to the extent it seeks the disclosure of information that is protected by the attorney-client privilege and/or work product immunity. Ethicon further objects to this Interrogatory to the extent it seeks information that is confidential, proprietary business information and/or trade secrets. Ethicon objects on the grounds that this interrogatory is not limited to any relevant time period.

Subject to and without waiving the foregoing Objections, and consistent with the Federal Rules, and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which

they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. Notwithstanding, set forth are some examples of documents, though not all of the documents, which have been produced to Plaintiffs that may fall within this interrogatory. *See, e.g.*, Copy Review Materials, ETH.MESH.00142081 -00149087 (Prod. 3); ETH.MESH.00154266-00170122 (Prod. 4); ETH.MESH.00311528-00311554 (Prod. 7); information regarding IFU documents, ETH.MESH.00521869-ETH.MESH.00523158 (Prod. 13), ETH.MESH.02340250 -ETH.MESH.02342290 (Prod. 27); documents regarding sales, marketing and professional education materials, ETH.MESH.02330766-ETH.MESH.02330777 and ETH.MESH.PM.000065-ETH.MESH.PM.000067 (Prod. 25); ETH.MESH.02342291-ETH.MESH.02345802 (Prod. 28); ETH.MESH.02346965-ETH.MESH.02347254 (Prod. 30); ETH.MESH.03456774 -ETH.MESH.03461142 (Prod. 34).

In addition, Plaintiffs in the New Jersey coordinated litigation, including Plaintiffs represented by MDL counsel, have deposed a number of witnesses whose testimony may be responsive to this interrogatory. Specifically:

- Dr. Piet Hinoul was deposed for 4 days under N.J. Rule 4:14-2(c).
- Catherine Beath has been deposed for 2 days under N.J. Rule 4:14-2(c).

In addition, numerous fact witnesses have been deposed regarding pelvic mesh IFUs, patient brochures, and professional education. In the area of Medical Affairs, these include Dr. Aaron Kirkemo, Dr. David Robinson, Dr. Charlotte Owens, and Dr. Martin Weisberg. In the area of Regulatory Affairs, these include Bryan Lisa, Sean O'Bryan, and Jennifer Paine. In the

area of Marketing, these include Scott Jones, Giselle Bonet, Lynn Hall, Kevin Mahar, Jonathan Meek, Paul Parisi, and Zenobia Walji.

To the extent they exist, Ethicon produced responsive custodial documents for each of these witnesses that may also have additional information responsive to Plaintiffs' Interrogatory. Ethicon is continuing to meet and confer with plaintiffs concerning information related to foreign regulatory submissions and information related to hernia mesh devices.

INTERROGATORY 6:

Provide the name and title of the Person employed by You who was primarily responsible for testing the safety, efficacy, sterility, and manufacturing standards of Pelvic Mesh Products for each year from 1999 to 2012.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 6:

Ethicon objects to Interrogatory No. 6 because, as worded, it is ambiguous, overly broad, and unduly burdensome. Ethicon objects to this request as vague insofar as it fails to define "primarily responsible." Further, a person "primarily responsible" (however defined) for an area or topic does not necessarily equate to the person with the most relevant knowledge. Ethicon further objects because "safety" is undefined. Many different departments, groups, and cross-functional teams have at least some impact on and/or share some responsibility for the safety and efficacy of pelvic mesh products. For example, these include, but are not limited to, Medical Affairs, Pre-Clinical, Clinical Studies, Research & Development, Manufacturing, Quality, Pharmacovigilance, compliance, and professional education. Listing the persons "primarily responsible" for "testing" the "safety" and "efficacy" of 11 different pelvic mesh products for 13 years is unduly burdensome and, as phrased, is essentially unanswerable.

Additionally, the interrogatory is objectionably vague in that it does not define what is meant by "sterility" or "manufacturing standards." Sterility is impacted in both the design aspects of a product as well as in manufacturing process aspects. Further, while there are similarities, each product has a different design history and a unique validated manufacturing process. Documents produced to date have included design and manufacturing validation protocols. Listing the persons "primarily responsible" for "testing" the "sterility" and "manufacturing standards" of 11 different pelvic mesh products for 13 years is likewise unduly burdensome and, as phrased, is essentially unanswerable.

Subject to and without waiving the foregoing Objections, counsel in the New Jersey coordinated proceeding have deposed 43 witnesses – with MDL counsel actively conducting or otherwise participating in many of those – eliciting information directly responsive to the information sought in this interrogatory. Ethicon refers Plaintiffs to those depositions. Further, consistent with the Federal Rule of Civil Procedure 33(d), and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory.

Subject to the objections, one group that shares primary responsibility for the safety and efficacy of pelvic mesh products is Medical Affairs. Relevant persons within Medical Affairs at different times include:

- Dr. Axel Arnaud: Scientific Director, Ethicon Europe (1999-2001); Scientific Director, Ethicon Europe (2001-2008); Director, Medical Affairs, Ethicon EMEA (2008 – present)
- Dr. Richard Isenberg: Director Medical Affairs, Ethicon EWHU (1999 – 2002)
- Dr. Martin Weisberg: Director of Medical Affairs, Ethicon (2001 – present)
- Dr. Charlotte Owens: Worldwide Medical Director, Gynecare (2003-2005)
- Dr. David Robinson: Medical Director Worldwide, EWHU (2005 – 2010)
- Dr. Aaron Kirkemo: Associate Medical Director, EWHU (2008-2010); Medical Director, EWHU (2010 – 2012)
- Dr. Piet Hinoul: Director Medical Affairs – Worldwide, Ethicon (2010-present)

Subject to the objections and in response to the request concerning the testing of sterility and manufacturing standards, the TVT line of products, Gynemesh PS, Prolift, Prolift +M, and Prosima undergo an ethylene oxide manufacturing process pursuant to protocols established by Ethicon that occurs during the final stages of the manufacturing lifecycle. Further, the TVT line of products, Gynemesh PS, Prolift, Prolift +M, and Prosima each undergo unique manufacturing lifecycles. Persons in the United States with relevant knowledge of the processes and protocols, include:

- James McGowan: Engineering Fellow – Sterilization (2012); Base Business, Sterilization Manager (2006 – 2012).
- Michael Wolfe: Plant Quality Assurance Manager, Ethicon (2007 – 2009); Director Quality Operations, Raw Materials Supply & External Ops, Ethicon (2009 – present).

INTERROGATORY 7:

If You or any Person employed by You or on your behalf is currently performing any Testing or Studies on Pelvic Mesh Products and its potential association or causal relationship with Complications, please set forth specifically for each test or Study:

(a) The start date of the study or test

(b) The anticipated end-date of the study or test

(c) The anticipated publication date of the study or test

(d) The anticipated dates for the disclosure to the FDA or others of any preliminary data or results from the study (please specifically identify those persons or agencies to whom disclosure will be made);

(e) The identity of the source of any funding for the study, in whole or in part, if the study is not wholly funded by You;

(f) All endpoints of those studies;

(g) documents concerning the studies you identified above;

(h) The basis for the decision to perform such studies;

(i) The identity of the persons employed by You who determined that such studies would be performed.

(j) Attach any and all documents relating to any of Your responses to this interrogatory.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 7:

Ethicon objects to Interrogatory No. 7 because, as worded, it is ambiguous, overly broad, and unduly burdensome.

Subject to and without waiving the foregoing Objections, and consistent with Federal Rule of Civil Procedure 33(d), and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. Notwithstanding,

set forth are some examples of documents, though not all of the documents, which have been produced to Plaintiffs that may include information responsive to this interrogatory. *See, e.g.,* relevant portions of productions 12, 33, 36, 39, 43, 54, 63 related to the trial master files; ETH.MESH.04476324 – 04529711 (Prod. 62); deposition testimony and custodial files of Dr. Jessica Shen and Dr. Judi Gauld. Additionally, see below:

1. Investigator: Dr. Withagen; A Prospective and Comparative Study of the Performance of Tension Free Vaginal Mesh + Monocryl (Prolift + M™) versus Conventional Vaginal Prolapse Surgery (The Netherlands)
    a. Start date: Q1 2011
    b. Anticipated end date: Q4 2014
    c. Anticipated publication date: 12-month data – Q2 2014; 24-month data – Q2 2015
    d. Anticipated date of FDA disclosure: N/A
    e. Non-Ethicon sources of funding: academic budget, reserve research funds
    f. Primary endpoint: Percentage of patients with objective anatomical success (POP stage <2) after 24 months
    g. Secondary Endpoint: Subjective improvement in quality of life will be measured by generic (EQ-5D,PGI-I) and disease-specific (UDI, DDI, IIQ and PFDI20) quality of life instrument. Sexual functioning will be measured by generic (FSFI) and disease specific (PISQ12) questionnaires. Complications will be monitored with special notice for pain (Mc Gill pain questionnaire). Recovery will be measured with the Recovery index 10. The economical endpoint is short term (2 year) incremental cost-effectiveness in terms of costs per additional year free of prolapse and costs per QALY gained.

2. Investigator: Dr. Hulder: ProViS (Prolift + M and Sexual Function) (Switzerland)
    a. Start date: Q2 2011
    b. Anticipated end date: Q4 2013
    c. Anticipated publication date: Q2 2014
    d. Anticipated date of FDA disclosure: N/A
    e. Non-Ethicon sources of funding: none
    f. Primary endpoint: Primary Endpoint: No worsening in vita sexualis (decrease in total score Female Sexual Function Index (FSFI-d) of ≤ 3.3; max. score = 36) measured at 12 months postoperatively compared to the preoperative score.
    g. Secondary Endpoints: No worsening in pain during sexual intercourse (decrease in weighted pain subscore FSFI-d of ≤ 1; max score = 6) measured at 12 months postoperatively compared to preoperative. Assessment of pelvic floor function using the validated German pelvic floor questionnaire (Deutscher Beckenboden-Fragebogen, validated German version of the Australian pelvic floor questionnaire) at 12 months postoperatively compared to preoperative. Assessment of patient's satisfaction at 12 months postoperatively using the visual

analogue scale (VAS), question regarding reoperation and patient global impression (PGI) question. Clinical Examination at 3 and 12 months postoperatively assessing mesh erosion and recurrent POP by speculum examination, palpation and assessment of POP-Q. Safety.

3. Investigator: Dr. Deprest: An institutional audit of the short term complications & medium term outcomes of patients undergoing laparoscopic sacrocolpopexy (LSC) for vault prolapse using polypropylene mesh of different weight. (Belgium)
    a. Start date: Q2 2012
    b. Anticipated end date: Q1 2013
    c. Anticipated publication date: Q2 2013
    d. Anticipated date of FDA disclosure: N/A
    e. Non-Ethicon sources of funding: Unknown
    f. Primary Endpoints: 1. the occurrence of operative complications: will be classified as either intra-operative or postoperative (within 3 months of operation), and as either major (re-admission or re-operation within 6 weeks, thromboembolism, spondylodiscitis) or minor (infectious signs, haemorrhage requiring transfusion without reintervention, urinary retention etc.). 2. Reintervention for prolapse in the same compartment, and this at any time point during follow up. The time point of reintervention will be a variable per se.
    g. Secondary Endpoints: Objective Success will be defined as: Achievement of a POP-Q score of ICS Stage ≤1, without re-intervention for POP or graft related complication at approximately 12 months. Postoperative graft related complications (GRC) will be (non-limitative list) de novo dyspareunia, resolution or continuance of pre-existing dyspareunia, incidence of chronic pain, occurrence of exposure, extrusion or any other complication as described recently, and any reintervention because of the above. Subjective Success assessed by the Patient Global Impression of Change (PGI-C) tool, which is a 5-point Likert scale, where the patients are asked the following question at the follow up visit: “Compared with how you were doing before your recent pelvic floor operation, would you say that now you are: “much better”, “a little better”, “about the same”, “a little worse” or “much worse”?”. P-QoL: assesses the severity of symptoms in patients with urogenital prolapse and their impact on 9 different quality of life domains with scores for each domain, ranging between 0 and 100.

4. Investigator: Dr. Philips: Prospective Evaluation of TVT Exact under Local Anaesthesia with / without Sedation: Patient Tolerability and Long-Term Efficacy (United Kingdom)
    a. Start date (awaiting ethical approval)
    b. Anticipated end date: Q3 2014
    c. Anticipated publication date: Q3 2015
    d. Anticipated date of FDA disclosure: N/A
    e. Non-Ethicon sources of funding: None
    f. Primary Endpoints: Patient Tolerability of procedure under local anaesthesia measured by patient pain score, measured by visual analogue scale during procedure and 3 hours post operative and patient acceptability scores: visual analogue scale and numerical scales.

g. Secondary Endpoints: analgesic requirements; sedation requirements; perioperative complications including: blood loss, bladder perforation, vascular injury, voiding disorder; patient time to discharge (length of stay); time to return to normal activities (recorded at 6 weeks f/up appointment); PGI-I score at 6 weeks post op. (12 and 24 month data also possible if funding available); ICIQ UI change in score preop to post op score (preop, 6 weeks (routine f/up). (12 and 24 month data also possible if funding available); ICIQ-OAB score at 6 weeks. (12 and 24 month data also possible if funding available); ICIQ-VAS score at 6 weeks. (12 and 24 month data also possible if funding available); Free text on surgeon's experience of new delivery system.

5. Investigator: Dr. Khandwala: TVT-Secur as an Office-Based Procedure (United States)
   a. Start date: Q4 2008
   b. End date: Q2 2012
   c. Anticipated publication date: Q4 2012
   d. Anticipated date of FDA disclosure: N/A
   e. Non-Ethicon sources of funding: None
   f. Primary endpoint: to assess feasibility and success of performing the TVT-Secur procedure in the office setting. Success will be defined as 50% improvement on the subjective symptom VAS in the 3-month visit.
   g. Secondary endpoint: will include the assessment of intra-operative and post-operative complications, post-operative pain assessment, and type of anesthesia, operative time, quality of life measurements and subject satisfaction.

6. Investigator: Dr. Corcos: Efficacy of a Combined Surgical and Pharmacological Therapy to Treat Mixed Urinary Incontinence (Canada)
   a. Start date: Q4 2007
   b. End date: Q4 2012
   c. Anticipated publication date: Q4 2013
   d. Anticipated date of FDA disclosure: N/A
   e. Non-Ethicon sources of funding: None
   f. Primary endpoint: Patient perceived cure or improvement: 1. cure being defined as an improvement of at least 90% of both scores of the IIQ7 and ICIQ-SF; 2. improvement being defined as improvement of at least 50% of the scores of both questionnaires IIQ7 and ICIQ+_Toc177533873-SF.
   g. Secondary Endpoints: 1. decrease in leakage (24-hour pad test); 2. decrease in number of episodes of incontinence, number of voids in 72 hours (voiding diaries); 3. Cough test; 4. patient's satisfaction evaluated with Likert Scale - 5 (worse than before) to +5 (no micturition problem); 5. treatment related complications and adverse effects. Sample size of 80 was no met; analysis being carried out on sample of 60 patients.

7. Investigator: Dr. Walters: Dynamic ultrasound evaluation of midurethral sling position and correlation to physical exam and symptoms (United States)
   a. Start date: Q3 2012
   b. Anticipated end date: Q4 2013

c. Anticipated publication date: Q1 2014
d. Anticipated date of FDA disclosure: N/A
e. Non-Ethicon sources of funding: Institution
f. Primary End Points: Primary outcomes: Palpability of the tape on vaginal exam; ultrasound measurements of the sling position angle.
    i. Palpability will be evaluated by a pelvic surgeon who will be blinded to the sling type, ultrasound findings and questionnaire answers.
    ii. Ultrasound measurements will be done by a trained investigator utilizing 3- and 4-D ultrasound technology.
g. Secondary End Points:
    i. Association between the tape position, palpability of the tape on vaginal examination and incontinence cure-rare after TVT, TOT or TVT-O procedures.
        1. Incontinence cure-rate, or sling effectiveness, will be determined based on the UDI-6 and ISI validated questionnaires. In addition PGI-I will be used to assess global well being.
    ii. Association between the tape position, palpability of the tape on vaginal examination and de-novo voiding dysfunction symptoms after TVT, TOT or TVT-O procedures.
    iii. Association between the tape position, palpability of the tape on vaginal examination and sexual function after TVT, TOT or TVT-O procedures.
        1. Sexual function will be assessed using FSFI validated questionnaire as well as additional specific questions assessing the sensation from the tape, dyspareunia, groin, suprapubic and general pelvic pain (see Appendix)
    iv. Association between the tape position, palpability of the tape on vaginal examination with partner's discomfort during the intercourse.
        1. Partner's discomfort will be assessed using a specific questionnaire (filled out by the study subject) aimed at assessing the sensation from the tape during intercourse, presence of associated pain, and effect on intercourse frequency and satisfaction.

8. Investigator: Dr. Ross: TVT management of stress incontinence in women: randomised trial of TVT Secur versus TVT (Canada)
    a. Start date: Q4 2007
    b. End date: Q4 2011
    c. Anticipated publication date: Q4 2012
    d. Anticipated date of FDA disclosure: N/A
    e. Non-Ethicon sources of funding: None
    f. Primary Endpoint: objective evidence of SUI will be obtained using a standard pad test undertaken at 12 months following surgery. Women will be considered cured if the pad weight gain is less than 1g over the test period.
    g. Secondary Endpoints: subjective symptom assessment will take place at 12 months after surgery. Subjective cure is defined as either "no" experience of stress incontinence, or if urine loss has been "no problem at all". Incontinence QOL will be assessed by UDI-6 at 6 weeks and 12 months. Sexual function will

> be assessed by PISQ-12 at 12 months. Expectations will be assessed at 12 months where subjects are asked if their surgical expectations were met. Return to normal activities will be assessed at 12 months. Voiding dysfunction will be assessed at 12 months using uroflow and postvoid residual evaluation at the end of the pad test. surgical complications will be captured for 12 months following surgery.

Members of the EWHU Investigator-Initiated Study Committee are responsible for reviewing and approving investigator-initiated study applications.

INTERROGATORY 8:

Identify each advertising firm, public relations firm, marketing firm or medical communications company you engaged to draft studies, market and/or advertise Pelvic Mesh Products, including the identity of the manager of your accounts.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 8:

Ethicon objects to Interrogatory No. 8 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Further, Ethicon objects on the grounds that this interrogatory is not limited to the relevant time period, and seeks information that is irrelevant.

Subject to and without waiving the foregoing Objections, and consistent with Federal Rule of Civil Procedure 33(d), and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. Notwithstanding, set forth is an example of information and documents, though not all of it, which have been produced to Plaintiffs that may include information responsive to this interrogatory. *See, e.g.,*

Deposition Tr. of Lynn Hall, March 1, 2012. (Tr. p. 168-171.); *see also* custodial productions for Giselle Bonet, Lynn Hall, Scott Jones, Kevin Mahar, Jonathan Meek, and Zenobia Walji.

INTERROGATORY 9:

Give the name, official capacity or position of those Persons employed or formerly employed by You who were responsible for communicating with the FDA and equivalent foreign Agencies Concerning Pelvic Mesh Products.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 9:

Ethicon objects to Interrogatory No. 9 because, as worded, it is ambiguous, overly broad and unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Ethicon objects because the interrogatory is not limited in time or scope. Ethicon further objects to this interrogatory on the grounds that it is overly broad, unduly burdensome and oppressive insofar as it seeks information relating to foreign regulatory activities. Ethicon is continuing to meet and confer with Plaintiffs concerning foreign regulatory submissions. Such information is neither relevant to the claims and defenses in this action nor reasonably calculated to lead to the discovery of admissible evidence.

Ethicon objects to this request as vague insofar as it fails to define the phrase, "responsible for communicating with the FDA." Communicating with FDA is a task performed by cross-functional teams, with multiple members performing different roles. Subject to and without waiving the foregoing Objections, and consistent with the Federal Rules, and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents

responsive to this interrogatory. *See* Ethicon's Response to Plaintiffs' Request for Production No. 15.

Subject to the objections, the following non-exhaustive list of Persons had some responsibility for communicating with FDA at different times for different pelvic mesh products:

- Sheryl Robinson Bagalio: Manager, Regulatory Affairs (2008); Project Manager, Regulatory Affairs (2007).
- Catherine Beath: VP Regulatory Affairs, Global Surgery Group (2012-present); Worldwide VP, Quality Assurance and Regulatory Affairs, Ethicon, Inc. (2001-2012).
- Christiana Bielinski: Director, Quality Systems & Compliance (2008 – 2012).
- Elizabeth K. Blackwood: Worldwide VP, Quality Assurance (2003).
- Cindy Crosby: Director, Regulatory Affairs (2004); Director, WW Regulatory Affairs (2004 – 2005); Director, Quality Systems & Compliance (2005 – 2008).
- Dr. Sergio Gadaleta: VP Worldwide Regulatory Affairs and Product Vigilance; (2008 - 2010); Director, Regulatory Affairs, Ethicon Products/ Gynecare (2004 – 2007).
- Patricia M. Hojnoski: Senior Project Manager, Regulatory Affairs, Gynecare (2002-2006).
- Gregory R. Jones: Director, Regulatory Affairs (1997-2003); Director, Regulatory Affairs/ Quality Assurance, Gynecare (2001 – 2003).
- Brian Kanerviko: Director, WW Regulatory Affairs, EWHU (2011 – 2012).
- Dan Lamont: Director, Post-Market Surveillance, Ethicon, Inc. (2010 – present); Manager, Worldwide Quality Engineering, Ethicon, Inc. (2008-2010).

- Susan Lin: Manager, Regulatory Affairs (2008 – present); Senior Project Manager, Regulatory Affairs (2004 – 2008) .
- Bryan Lisa: Associate Director, Regulatory Affairs (2009-2010).
- Iris Magalhaes: Director, Quality Assurance, WW Quality Engineering, Ethicon.
- Sean O'Bryan: Senior Project Manager, Regulatory Affairs (2001-2005).
- Jennifer Paine: Worldwide Director, Regulatory Affairs (2007-2008); Manager, Regulatory Affairs (2005-2007); Senior Project Manager, Regulatory Affairs (2004-2005).
- John D. Paulson: Vice President, Regulatory Affairs/ Quality Assurance (1997 – 2001).
- Mark Yale: Group Director, Franchise Quality Engineering, Quality Systems and Post Market Surveillance (2009-2010); Director, Worldwide Risk Management and Quality Engineering (2005-2009).

INTERROGATORY 10:

Please state the name, address, phone number, official capacity and/or position, and a brief description of their job responsibilities, of those persons employed or formerly employed by you who were responsible for or in charge of the following departments, between 1999 and the present:

(a) Regulatory affairs/compliance

(b) Toxicity and pigment testing;

(c) Engineering

(d) Strength/Tensile strength testing

(e) Machining;

(f) Porosity (space between mesh pores) testing

(g) Epidemiology and outcome studies;

(h) Marketing;

(i) Manufacturing;

(j) Sales;

(k) Safety and efficacy; and

(l) Supply Chain Management;

SUPPLEMENTAL RESPONSE TO INTERROGATORY 10:

Ethicon objects to Interrogatory No. 10 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Ethicon objects to this request as vague insofar as it fails to define "responsible for or in charge of." Responsibilities in the different departments are tasks performed by cross-functional teams, with multiple members performing different roles. Further, a person "responsible for or in charge of" (however defined) for an area or topic does not necessarily equate to the person with the most relevant knowledge. Furthermore, several of the departments listed in the interrogatory do not exist as named. For example, as phrased in the interrogatory, there is no Toxicity and Pigment Testing Department, no Strength/ Tensile Strength Testing Department, no Machining Department, no Porosity (Space Between Mesh Pores) Testing Department, no Epidemiology and Outcomes Studies Department, and no Safety and Efficacy Department.

Subject to and without waiving the foregoing Objections, and consistent with Federal Rule of Civil Procedure 33(d), and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic

production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory.

Subject to and without waiving the foregoing Objections, Ethicon states that the following, non-exhaustive list of Persons share responsibilities within different departments at different times for different pelvic mesh products related to the topics set out in the sub-paragraphs:

(a) Regulatory affairs/compliance:

a. Catherine Beath: VP Regulatory Affairs, Global Surgery Group (2012-present); Worldwide VP, Quality Assurance and Regulatory Affairs, Ethicon, Inc. (2001-2012).

b. Rick Sedlatschek: VP Quality Assurance and Regulatory Compliance (2012 – present)

(b) Toxicity and pigment testing:

a. There is no "Toxicity and Pigment Testing Department." A non-exhaustive list of persons in the United States with relevant knowledge of the topics as related to pelvic mesh products includes:

i. Thomas Barbolt: Distinguished Research Fellow – Toxicologist/ Pathologist (2006 – 2008); Senior Research Fellow – Toxicologist/ Pathologist (2000-2006); Research Fellow – Toxicologist/ Pathologist (1997 – 2000)

ii. Rich Hutchinson: Toxicology Risk Assessor (CV produced; Plaintiffs' Exhibit 542, New Jersey)

(c) Engineering:

a. There is no "Engineering Department." A non-exhaustive list of persons in the United States with relevant knowledge of the topic as related to pelvic mesh products includes:

i. Scott Ciarrocca: Associate Director, EWHU R&D (CV produced; Plaintiffs' Exhibit 612).

ii. Paul DeCosta, Associate Director R&D (2006 – 2008); Director R&D, EP (2008 – 2012).

iii. Jeff Everett: Manager, Quality New Product Development, Lifecycle Management (CV produced; Plaintiffs' Exhibit 726, New Jersey).

iv. Christophe Mauge: Group Director, EWHU R&D (2007 – present).

v. Dan Smith: Principal Engineer (2002-2005); Principal Engineer R&D (2005 – 2007); Senior Principal Engineer R&D, Engineering Fellow, EWHU (2007 – present).

vi. Rohinton Toddywala: VP R&D, Gynecare (2001 – 2005); Director, Product Development Elctr/Msh (2005); Director & Venture Leader (2006); VP Internal Ventures (2006 – 2008).

vii. Cliff Volpe: Associate Director, EWHU R&D (2002 – 2012) (CV produced; Plaintiffs' Exhibit 1018, New Jersey).

(d) Strength/Tensile strength testing:

a. There is no "Strength/ Tensile Strength Testing Department." A non-exhaustive list of persons in the United States with relevant knowledge of the topic as related to pelvic mesh products includes:

i. Elizabeth Vailhe: Staff Scientist, Ethicon (2008 – present); Senior Scientist, Ethicon (2004 – 2008); Scientist, Ethicon (2000 – 2004).

(e) Machining:

There is no "Machining Department." Further, the term is undefined and sufficiently vague so as to make this sub-paragraph unanswerable.

(f) Porosity (space between mesh pores) testing:

a. There is no "Porosity Testing Department." A non-exhaustive list of persons in the United States with relevant knowledge of the topic as related to pelvic mesh products includes:

i. Daniel Burkley: Principal Scientist, Analytical Characterization Group.

(g) Epidemiology and outcome studies:

a. There is no "Epidemiology and Outcome Studies Department." A non-exhaustive list of persons with relevant knowledge of clinical studies related to pelvic mesh products includes:

i. Jessica Shen: Director, Clinical Development WW (CV produced; Plaintiffs' Exhibit 2000, New Jersey).

ii. Judi Gauld: Associate Director, Clinical Development (2009-present); Manager, Clinical Research (2005-2009); Senior Product Manager (2001-2005).

(h) Marketing:

a. A non-exhaustive list of persons with relevant knowledge of the topic related to pelvic mesh products includes:

i. Giselle Bonet: (CV produced; Plaintiffs' Exhibit 402, New Jersey).

ii. Lesley Fronio: VP, Worldwide Marketing, Ethicon (2008 - present); Group Director, WW Marketing (2007); Group Director, WW Marketing EP (2006); Group Director, WW Marketing (2005).

iii. Lynn Hall: (CV produced; Plaintiffs' Exhibit 401, New Jersey).

iv. Matt Henderson: VP, U.S. Sales & Marketing, Ethicon EWHU (2012 – present).

v. Price St. Hilaire: Division Sales Manager (2001 – 2005); Product Director (2005 – 2007); WW Director, Marketing (2007); Group Product Director (2007 – 2008).

vi. Scott Jones: Product Director, Pelvic Floor Repair (2008 - 2011); Product Director, Incontinence Platform (2011- 2012) (CV produced, New Jersey).

vii. Brian Luscombe: Manager, Business Development (1999-2001); Product Director (2001 – 2004).

viii. Kevin Mahar: (CV produced; Plaintiffs' Exhibit 560, New Jersey).

ix. Jonathan Meek: (CV produced; Plaintiffs' Exhibit 310, New Jersey).

(i) Manufacturing:

There is no "Manufacturing Department." *See* Response to Interrogatory No. 6.

(j) Sales:

a. A non-exhaustive list of persons with relevant knowledge of the topic as related to pelvic mesh products includes:

i. Matthew T. Henderson: VP, U.S. Sales & Marketing, Ethicon EWHU (2012 – present).

ii. Kevin Mahar: (CV produced; Plaintiffs' Exhibit 560, New Jersey).

(k) Safety and efficacy:

a. *See* response to Interrogatory No. 6.

(l) Supply Chain Management:

a. A non-exhaustive list of persons in the United States with relevant knowledge of the topic includes:

i. Caleb Dailey: Manager, Operations Engineer (1999-2002); Program Manager (2002-2004); Director, Strategic Planning Operations (2004); Director Portfolio Management & Planning (2005); Director, Portfolio Management (2006); Director, Project Management (2007 – present).

ii. Michael Wolfe: Plant Quality Assurance Manager, Ethicon (2007 – 2009); Director Quality Operations, Raw Materials Supply & External Ops, Ethicon (2009 – present).

INTERROGATORY 11:

If You met or conferred with any Person, other than Johnson & Johnson, Inc. or Ethicon Inc. employees, to discuss whether there was an association or causal relationship between Pelvic Mesh Products and any Complications, please:

(a) Identify the dates and attendees of each such meeting or communication;

(b) Identify what was discussed or presented in connection with or during each meeting or communication;

(c) Produce all documents relating to the meeting or communication.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 11:

Ethicon objects to Interrogatory No. 11 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Ethicon further objects to this Interrogatory to the extent it seeks the disclosure of information that is protected by the attorney-client privilege and/or work product immunity. Ethicon objects on the grounds that this interrogatory is not limited to the relevant time period, and seeks information that is irrelevant.

Subject to and without waiving the foregoing Objections, and consistent with Federal Rule of Civil Procedure 33(d), and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. Notwithstanding, set forth are examples of information and documents, though not all of it, which have been produced to Plaintiffs that may include information responsive to this interrogatory. *See* custodial files productions/ depositions/ deposition exhibits for Dr. Piet Hinoul, Dr. David Robinson, Dr. Martin Weisberg, Dr. Aaron Kirkemo, Dr. Charlotte Owens, Dr. Axel Arnaud, Dr. Judi Gauld, and Dr. Jessica Shen; *see also* Response to Interrogatory No. 7; Ethicon's Responses to Plaintiffs' Requests for Production of Documents Nos. 4, 28, 43.

INTERROGATORY 12:

If during or after the time that you marketed, sold, distributed or produced Pelvic Mesh Products, You were aware of any Manufacturing Defects or Defects of any kind please identify:

(a) The nature and extent of the Defect

(b) The day you first became aware of the Manufacturing Defect;

(c) The start date when the Defect occurred;

(d) The date when the Defect was resolved;

(e) The dates of the disclosure to the FDA or other Agencies, if any

(f) Whether or not there was a recall as a result of the Defect;

(g) The identity of the persons employed by You who determined that such Defects existed;

(h) Attach any and all documents relating to any of Your responses to this interrogatory.

RESPONSE TO INTERROGATORY 12:

Ethicon objects to Interrogatory No. 12 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Further, Ethicon objects to the interrogatory to the extent it calls for a legal conclusion by use of the word "Defect."

Subject to and without waiving the foregoing Objections, and consistent with Federal Rule of Civil Procedure 33(d), and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. Notwithstanding, set forth is an example of information and documents, though not all of it, which have been produced to Plaintiffs that may include information responsive to this interrogatory. *See* Ethicon's Responses to Requests for Production Nos. 15 and 19; *see* ETH.MESH.00066921, ETH.MESH.00330835 - 839, ETH.MESH.00874797; *see also* custodial productions/ depositions/ deposition exhibits for Catherine Beath, Jennifer Paine, Mark Yale, Dan Lamont, and Bryan Lisa.

Subject to the foregoing, regarding specific recalls that occurred, Ethicon further submits the following response:

- In 2000, Ethicon recalled six lots of TVT implicating 5,440 units following complaints of a "needle pulloff" during the surgery. Ethicon notified FDA in September 2000. Most of the recalled lots had an expiration date of 2005.

- In January of 2007, Prolift Lot 2990052 was recalled, affecting 40 boxes. The units were recalled because, due to a packaging error, some kits were labeled as Prolift Total when they were Prolift Anterior. The impact of the error was minimal, as the only known effect was a one-hour delay in a single surgery while the proper material could be obtained from another hospital.

INTERROGATORY 13:

For each year from 1999 to the present, state the total number of employees You had in:

(a) the sales and marketing departments

(b) the regulatory and safety departments

SUPPLEMENTAL RESPONSE TO INTERROGATORY 13:

Ethicon objects to Interrogatory No. 13 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Ethicon objects on the grounds that this interrogatory is not reasonably limited to any relevant time period, and seeks information that is irrelevant. It is not reasonably limited in scope to employees involved with pelvic mesh products. Ethicon further objects because "safety" is undefined. Many different departments, groups, and cross-functional teams have at least some impact on and/or share some responsibility for the safety of pelvic mesh products. For example, these include, but are not limited to, Medical Affairs, Pre-Clinical, Clinical Studies, Research & Development, Manufacturing, Quality, Pharmacovigilance, compliance, and professional education.

Consistent with the Federal Rules, and the Protective Order entered by the Court, documents responsive to this interrogatory, to the extent they exist, have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules,

Plaintiffs can locate the particular electronic documents responsive to this interrogatory to the extent they exist.

INTERROGATORY 14:

State the name(s), title, address and phone number of each individual who prepared or assisted in the preparation of these interrogatories.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 14:

Ethicon objects to this Interrogatory on the basis that it is vague, ambiguous, and overbroad. Ethicon further objects to this Interrogatory on the ground that it seeks information that is protected by the attorney-client privilege and/or work product immunity. Ethicon further objects to this Interrogatory to the extent it seeks the disclosure of information that is protected by the attorney-client privilege and/or work product immunity. Subject to and without waiving the foregoing Objections, Ethicon states that these responses were prepared by counsel for Ethicon based upon pleadings, deposition transcripts, and documents obtained in discovery or provided by Ethicon employees. Counsel for Ethicon has in addition consulted with Dr. Judi Gauld and Catherine Beath regarding the responses to these interrogatories.

INTERROGATORY 15:

When did You acquire information that provided evidence of a reasonable association between Pelvic Mesh Products and any Complications.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 15:

Ethicon objects to Interrogatory No. 15 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Consistent with the Federal Rules, and the Protective Order entered by the Court, documents responsive to this interrogatory, to the extent they exist, have been produced to

Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. Further, any such evidence if it exists would be equally available to Plaintiffs in the form of data from published medical literature regarding pelvic mesh products. *See* Custodial Productions/ depositions of Dr. Piet Hinoul, Dr. David Robinson, Dr. Charlotte Owens, Dr. Aaron Kirkemo, Dr. Judi Gauld, Dr. Jessica Shen; *see also* Responses to Interrogatories 3, 4, and 5.

INTERROGATORY 16:

When did You acquire information that provided evidence of a causal association between Pelvic Mesh Products and any Complications.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 16:

Ethicon objects to Interrogatory No. 16 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Ethicon further objects to the interrogatory because, as phrased, it assumes a "causal association" exists. Subject to and without waiving the foregoing Objections, Ethicon states that any such evidence if it exists would be equally available to Plaintiffs in the form of data from published studies regarding the Pelvic Mesh Products. Ethicon also refers to its Response to Interrogatory 15.

INTERROGATORY 17:

Please identify each electronic database (including but not limited to the name of the database, date ranges, size, data map/schema operating system and interface application) utilized by you concerning:

(a) Adverse event reports or medical device reports;

(b) Sales and sales training;

(c) Marketing;

(d) Regulatory compliance;

(e) Key opinion leaders, preceptors, investigators, members of your speakers bureau and product champions;

(f) Communications with physicians or other healthcare providers;

(g) Studies;

(h) Design Failure Mode and Effects Analyses;

(i) Risk assessment or analysis;

(j) Design changes;

(k) Record retention;

(l) Complaints or reports of injuries; and

(m) Trending of adverse events.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 17:

Ethicon objects to Interrogatory No. 17 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Ethicon further objects to this Interrogatory to the extent it seeks information that is confidential, proprietary business information and/or trade secrets. Ethicon objects on the grounds that this interrogatory is not limited to the relevant time period, and seeks information that is irrelevant. Without waiving these objections, Ethicon states as follows:

The relevant program, the type of application and the responsible department of Ethicon is as follows:

(a) Adverse event reports or medical device reports:

CHATS (Remetrex) Database 2; Database; Quality Systems

(b) Sales and sales training:

2009 Ethicon Franchise Strat Plan SharePoint 17; Sharepoint; Strategic Marketing
Clinical Expertise.com; Website; Clinical Education; Professional Education
Copy Review Paper Files Box 16; Paper File; Marketing
eClinical Compendium for Sales Rep; EDR; Marketing
EVIA Reporting; Database; Sales Marketing
EWH&U Sales Training eRoom20; eRoom; Sales
EWHU Sales Northeast Region; SharePoint; Sales
Finance EWH&U SharePoint; Sharepoint; Finance
Finance/GPD; GroupShare; Finance
Gateway Commerce System Database 7; Database; Sales
Goldmine; Database; Sales
HPIS-Product Data; Database; Unknown
Optimizer; Database; Sales
Sales & Marketing/Gynecare GS8; GroupShare; Marketing
Sales & Mktg/Groups/Common/Women's Health Urology GS9; GroupShare; Sales Training
Sales & Marketing/lynnhall/TVT; GroupShare; Sales Training
Strategic Plan SharePoint; SharePoint; Finance
Strategic Planning; Database; Unknown
Sales Inquiry Tool; Database; Sales
Sales Learning & Development Team Site SharePoint 23; SharePoint; Sales Training
Sales Learning & Development Web Portal Website 13; Website; Sales Learning & Dev.

(c) Marketing:

Austrian Gynecare website; Website; Marketing
Beat Prolapse and SUI.com; Website; Marketing
Beat Prolapse.com; Website; Marketing
Beat SUI.com; Website; Marketing
Belgian Gynecare website; Website; Marketing
Copy Review Paper Files Box 16; Paper File; Marketing
D'Art Launch eRoom 13; eRoom; Marketing
eCatalog; Website; Sales
EES Latin American/EES Women's Health; SharePoint; Marketing
EMEA SharePoint; SharePoint; EMEA Marketing
Ethicon Women's Health & Urology eRoom (EU); eRoom; Marketing
Ethicon.com; Website; Marketing
Ethicon360 EMEA; Website; Marketing
Ethicon360.com; Website; Marketing
EWH&U EMEA Marketing; eRoom; Medical Affairs
EWHU Marketing SharePoint; SharePoint; Marketing
EWHU NPD Project SharePoint 16; SharePoint; R&D

EWHU SharePoint 5; SharePoint; Marketing
French Gynecare Website; Website; Marketing
German Gynecare website; Website; Marketing
GGM/GGM Blue (https://jnjblue.schawk.com/jnjblue/spmvc/login); Database; Marketing
Gynecare Incontinence & Pelvic Floor Repair eRoom 4; eRoom; Marketing
Gynecare Market Research Team eRoom 16; eRoom; Marketing
Gynecare.com Website 1; Website; Marketing
Literature Depot Website 10; Website; Sales Marketing
Marketing Paper Files box 13; Paper File; Marketing
My Preceptor.com website 8; Website; Professional Education
Netherland Gynecare Website; Website; Marketing
Pelvic Floor Repair Shared Documents SharePoint 1; SharePoint; Marketing
Pelvic Health Solutions.com Website 2; Website; Marketing
Project Tomorrow SharePoint; SharePoint; Marketing
Sales & Marketing/EWH&U/2006 Conventions GS; GroupShare; Marketing
Sales & Marketing/Groups GS 14; GroupShare; Sales Learning & Dev.
Sales & Marketing/Linda Linton GS; GroupShare; Marketing
South African Pelvic Health Solutions Site; Website; Marketing
Strategic Marketing eRoom 15; eRoom; Marketing
Swiss Gynecare Website; Website; Marketing
Thunder eRoom 21; eRoom; Medical Affairs
UK Ethicon Products Website; Website; Marketing
UK EWHU Website; Website; Marketing
UK Womens Health Solutions; Website; Marketing
Whats Happening Down There.com Website 6; Website; Marketing
WW Marketing eRoom 12; eRoom; Marketing
WW Marketing SharePoint 29; SharePoint; Sales Training & Dev.
www.ethiconbiosurgerycatalog.com; Website; Unknown

(d) Regulatory compliance:

Compliance Wire; Database; QA
ECCS Engineering Change Control System (Matrix One)/DMS EDR 4; EDR; Regulatory R&D
EU Health Care Compliance; GroupShare; MD&D Regional Offices EMEA
EWHU Regulatory Sharepoint 25; Sharepoint; Regulatory
GGM LCA Archive Folder; GroupShare; WW Product Labeling
Global Audit Management System (GAMS); Database; QA
HCC Life; Database; MD&D Regional Offices EMEA
International Registration Requests Tool; Database; Regulatory Affairs, MD&D

International Regulatory Share Point 20; SharePoint; Regulatory
Labeling Control System (Agile) Database 1; Database; Regulatory Manufacturing
Regulatory Affairs; GroupShare; Regulatory
Regulatory Affairs eRoom 2; eRoom; Regulatory
Regulatory Affairs Scanned Paper Files EDR 5; EDR; Regulatory
Regulatory Affairs/REGULATORY AFFAIRS/Somerville/Litigation Hold GS7; GroupShare; Regulatory
Regulatory Affairs/REGULATORY AFFAIRS/Somerville/RA STRATEGIES DATABASE GS 6; GroupShare; Regulatory
Regulatory Affairs/REGULATORY AFFAIRS/Somerville/RA SUBMISSIONS DATABASE-SUBMITTED TO FDA/EWH&U GS 5; GroupShare; Regulatory
Scanned Product Labeling Documents; GroupShare; WW Product Labeling
Thunderbird Artwork System; EDR; R&D

(e) Key opinion leaders, preceptors, investigators, members of your speakers bureau and product champions:

Accurate; Database; Professional Education
EWH&U Professional Education eRoom 1; Professional Education
Global Professional Education Portal 15; Website; Professional Education
My Preceptor.com Website; Website; Professional Education
Prof Ed/EWHU Sharepoint 36; SharePoint; Professional Education
Professional Education on Shared Drive GS 4; GroupShare; Professional Education
Professional Education Registration System, Website 4; Website; Professional Education
Professional Education Speaker Contracts; Paper File; Professional Education
WW Prof Ed eRoom 26; eRoom; Professional Education
WW Prof ED SharePoint 8; SharePoint; Professional Education
WW Professional Education TOOLBOX SharePoint9; SharePoint; Professional Education

(f) Communications with physicians or other healthcare providers:

Clinical Expertise.com; Website; Professional Education
ETH Medical Affairs SharePoint 15; SharePoint; Medical Affairs
Exact Target; Database; Marketing
Medical Information Requests System; SharePoint; Medical Affairs

(g) Studies:

Clinical Development (EBM) Team Site SharePoint 14; SharePoint; Clinical Development
Clinical Development/Ailie Smith; GroupShare; Clinical Development
CPC eRoom 29; eRoom; Preclinical
ETH Medical Affairs SharePoint 15; SharePoint; Medical Affairs
EU Clinical Research Data Entry; GroupShare; MD&D
GLP Archive; Paper File; Preclinical
GMBH R&D External Drive; Hard Drive; R&D
GMBH R&D Paper File; Paper File; Preclinical
Hutchinson/Biocompatability Strategies; GroupShare; Preclinical
IIS Review Committees SharePoint 13; SharePoint; Medical Affairs
Oracle Database 4; Database; Clinical Development
Pre-Clinical Study Management System (TOPAZ); Database; Clinical Development
Product Performance Evaluation SharePoint 26; SharePoint; Performance Evaluation
PSE/CPC Central File Paper Paper 6; Paper File; Preclinical
Trial Master File Box 20, 21, 22, 23, 24, 25, 26, 27; Paper File; Clinical Development
Trial Master File; Microfilm and Scanned Paper EDR3; EDR; Clinical Development

(h) Design Failure Mode and Effects Analyses:

Adaptiv; EDR; QA
CAPA SharePoint 22; SharePoint; Quality Systems
Design History Files; eDHF EDR 1; EDR; R&D
DHF Scanned Paper Files EDR 2; EDR; R&D
ECCS Engineering Change Control System (Matrix One)/DMS EDR 4; EDR; Regulatory R&D
EVITA; EDR; R&D; QA
Product Lifecycle Management System (eDHF, NCR, CAPA); EDR; Quality Systems

(i) Risk assessment or analysis:

Adaptive; EDR; QA
CAPA SharePoint 22; Quality Systems
Corrective and Preventive Action; Database; Quality Systems
EWH&U Management Project Updates eRoom 8; eRoom; R&D
PQI Paper Files Box 15; Paper File; Quality Systems
Product Lifecycle Management System (eDHF, NCR, CAPA); EDR; Quality Systems
Quid 1; Database; Unknown
Risk Management Legal Review Paper Files; Paper File; Legal

(j) Design changes:

Adaptive; EDR; QA
Design History Files; eDHF EDR 1; EDR; R&D
DHF Scanned Paper Files EDR 2; EDR; R&D
EVITA; EDR; R&D; QA
EWH&U Management Project Updates eRoom 8; eRoom; R&D
EWHU Incontinence SharePoint 19; SharePoint; R&D
EWHU Pelvic Floor SharePoint 7; SharePoint; R&D
R&D/Gynecare R&D/D'Art GS 1; GroupShare; R&D
RD Continence Health Portfolio Management Team SharePoint 10; SharePoint; R&D
RD ESHU TVT Retropubic Refresh- TVT Exact SharePoint 11; SharePoint; R&D
RDCAD/D'Art GS2; GroupShare; R&D
RDCAD/DHF0000253 Prolift expiry update GS 3; GroupShare; R&D
RDCAD/TVT-SECUR GS 10; GroupShare; R&D
RDEWHU SharePoint 6; SharePoint; R&D
Thunder eRoom 21; eRoom; Medical Affairs
Thunder SharePoint 12 (tpro); SharePoint; R&D

(k) Record retention:

Adaptiv; EDR; QA
ECCS Engineering Change Control System (Matrix One)/DMS EDR4; EDR; Regulatory; R&D

(l) Complaints or reports of injuries:

CHATS (Remetrex) Database 2; Database; Quality Systems
Ethicon Customer Quality Information eRoom 5; Quality Systems
Post Market Surveillance Sharepoint 3; SharePoint; Quality Systems
PQI Paper Files Box 15; Paper File; Quality Systems
QA Complaint Investigation Reports; GroupShare; WW Customer Quality
QA SharePoint 4; SharePoint; Quality Systems
World Wide Quality eRoom 6; eRoom; Quality Systems

(m) Trending of adverse events:

Enterprise Data Warehouse; Database
QUID 1; Database; Quality Systems
QUID 2 Database 3; Database; Quality Systems

Ethicon further directs Plaintiffs to the December 7, 2011 Deposition of James Mittenthal in the coordinated New Jersey proceeding.

INTERROGATORY 18:

For each of the Pelvic Mesh Products, please identify all testing you conducted, sponsored or funded concerning the:

(a) Measurement or the potential for and amount of in vivo (human or animal) shrinkage;

(b) Measurement or the potential for and amount of in vivo (human or animal) creep;

(c) Measurement or the potential for and amount of in vivo (human or animal) physical or mechanical changes;

(d) Measurement or the potential for and amount of physical or mechanical forces in the human female pelvic floor;

(e) Measurement or the potential for and amount of anticipated stresses in the human female pelvis;

(f) Measurement or the potential for and amount of in vivo (human and animal) movement due to the body's reaction to the mesh;

(g) Determination of a physician or other healthcare provider's proper course of action in the event of any failure or malfunction in vivo (human or animal).

(h) Human tissue elastic properties, including such properties in the human female pelvis; and

(i) Human or animal pelvis.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 18:

Ethicon objects to Interrogatory No. 18 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Ethicon objects on the grounds that this interrogatory is not limited to the relevant time period, and seeks information that is irrelevant.

Subject to and without waiving the foregoing Objections, and consistent with Federal Rule of Civil Procedure 33(d), and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs

in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. Notwithstanding, set forth are some examples of documents, though not all of the documents, which have been produced to Plaintiffs that may fall within this interrogatory. *See, e.g.* Custodial Productions for Dr. David Robinson; Dr. Piet Hinoul; Dr. Aaron Kirkemo; Dr. Judi Gauld; Dr. Jessica Shen; Dr. Martin Weisberg; and Dr. Charlotte Owens (deposition/ exhibits), Scott Ciarrocca, Maggie D'Aversa, Jeff Everett, Cliff Volpe, Vincenza Zaddem. In addition, Defendants have produced central source files related to the pre-clinical and clinical development of relevant pelvic mesh devices and information responsive to the interrogatory may be found therein. *See* Prods. 22, 26, 31, 32, 33, 37, 43, 54, 57; *see also* Ethicon's Response to Request for Production No. 15.

INTERROGATORY 19:

Please state whether any of your pelvic mesh products are not suitable for any particular patient populations. For each such patient population, please state:

(a) The specific patient population for which your pelvic mesh product is not suitable, and the reasons why these products are not suitable for the particular patient population;

(b) When you became aware that such patient population was not an appropriate candidate for your pelvic mesh product(s);

(c) The date and manner in which you conveyed this information to physicians and/or patients;

(d) What actions you took to ensure that patients in the particular patient populations did not receive the pelvic mesh product.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 19:

Ethicon objects to Interrogatory No. 19 because, as worded, it is ambiguous, overly broad, unduly burdensome

Subject to and without waiving the foregoing Objections, and consistent with Federal Rule of Civil Procedure 33(d), and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. Additionally, the Contraindications contained in the IFUs for the relevant pelvic mesh products advise physicians of the persons for whom the products are not suitable. Any further patient selection criteria is patient-specific and is a determination best made by the particular patient's physician in consultation with the patient.

INTERROGATORY 20:

Please identify each individual involved in the decision to cease market withdrawal of any of your pelvic mesh products, and the precise reasons that you withdrew each such product from the market.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 20:

Ethicon objects to Interrogatory No. 20 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. In addition, Ethicon objects to the use of the word "withdrawal," as it implies a recall of the subject products, which has not occurred. Ethicon objects to the interrogatory as overbroad to the extent it asks for the identity of "each individual" "involved" in the decision. Ethicon further objects to this Interrogatory to the extent it seeks the disclosure of information that is protected by the attorney-client privilege and/or work product immunity.

Subject to and without waiving the foregoing Objections, persons involved in the decision to discontinue commercialization in the United States include Charles E. Austin (Company Group Chairman, General Surgery), Timothy Schmidt (President, U.S. General Surgery), and Catherine Beath (Vice President Regulatory Affairs, Global Surgery Group). As to the reasons for the discontinuation, Ethicon states that it believes that the products are safe and effective options for women. Ethicon arrived at the decision to stop commercialization of the products after considering the commercial viability of the products in the United States in light of the complexities of the clinical study requirements, the significant adverse publicity, and the litigation environment. The size and the competitiveness of the market place and the availability of other treatment options for women were also factors in the decision

Further, consistent with Federal Rule of Civil Procedure 33(d), and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. Notwithstanding, set forth are some examples of documents, though not all of the documents, which have been produced to Plaintiffs that may contain information responsive to this interrogatory. *See* Prod. 53 (ETH.MESH.04005088 – ETH.MESH.04005096); Prod. 61 (ETH.MESH. 04474273 – 04476322); Prod. 64 (ETH.MESH.04542554 – ETH.MESH.04568735); Prod. 65 (ETH.MESH. 04568736 – ETH.MESH.04666998); Prod. 66 (ETH.MESH.04666999 - ETH.MESH.04680216); Prod. 67 (ETH.MESH.04680217 – ETH.MESH.04680328).

INTERROGATORY 21:

For each of your pelvic mesh products, provide the specific dates of use for each of the following items:

(a) Instructions for Use

(b) Directions for Use

(c) Patient Brochures

(d) Sales training materials

(e) Physician training material

(f) Direct to Consumer Advertising

(g) Sales aids, physician leave behinds and physician marketing materials.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 21:

Ethicon objects to Interrogatory No. 21 because, as worded, it is ambiguous, overly broad, and unduly burdensome. Subject to and without waiving the foregoing Objections, and consistent with the Federal Rules, and the Protective Order entered by the Court, documents that may be responsive to this interrogatory to the extent they exist have been produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this interrogatory. S*ee* Ethicon's Response to Interrogatory 2.

INTERROGATORY 22:

Please state when YOU first became aware of the criminal investigation of Ethicon, Inc. related to YOUR Pelvic Mesh Products and/or Hernia Mesh Products and identify any and all employees who were involved with that or any other criminal investigation related to YOUR conduct in the area of Pelvic Mesh Products and/or Hernia Mesh Products.

SUPPLEMENTAL RESPONSE TO INTERROGATORY 22:

Ethicon objects to Interrogatory No. 22 because, as worded, it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Ethicon objects to the production of information regarding hernia mesh as irrelevant to this litigation involving pelvic mesh. Ethicon further objects to this Interrogatory to the extent it seeks the disclosure of information that is protected by the attorney-client privilege and/or work product immunity. Ethicon also objects to this Interrogatory to the extent it calls for confidential patient information protected from disclosure under the applicable federal regulations.

Subject to and without waiving the foregoing Objections, the only information of which Ethicon is aware regarding any criminal investigation is that identified in the deposition of Daniel Minsker taken on July 13, 2012, or in oblique references in letters to Ethicon by persons identified in the Minsker deposition.

This the 8th day of April, 2013.

Respectfully submitted,

/s/Christy D. Jones

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ATTORNEYS FOR DEFENDANT ETHICON, INC.

CERTIFICATE OF SERVICE

I hereby certify that the above and foregoing has been served on counsel for Plaintiffs via electronic mail this the 8th day of April, 2013.

/s/ Kari L. Sutherland

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